GOVERNMENT OF INDIA
AYURVEDA,YOGA & NATUROPATHY,UNANI,SIDDHA AND HOMEOPATHY (AYUSH)
LOK SABHA

UNSTARRED QUESTION NO:2973
ANSWERED ON:02.12.2016
Central Drug Controller for AYUSH
Tharoor Dr. Shashi

Will the Minister of AYURVEDA,YOGA & NATUROPATHY,UNANI,SIDDHA AND HOMEOPATHY (AYUSH) be pleased to state:

Will the Minister of AYURVEDA, YOGA AND NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY (AYUSH) be pleased to state:

(a) whether progress has been made towards the creation of a Central Drug Controller for AYUSH (CDCA) drugs, which seeks to standardise quality and safety measures for AYUSH drugs;

(b) if so, the details thereof and if not, the reasons therefor;

(c) whether the Government has taken measures to expedite the process to finalise and establish the CDCA, which would carry out functions including the approval of new drugs, establishing standards for clinical trials and safeguarding public health by assuring the safety, efficiency and quality of medicines;

(d) if so, the details thereof; and

(e) if not, the reasons therefor?

Answer

ANSWER
THE MINISTER OF STATE (IC) OF THE MINISTRY OF AYURVEDA,
YOGA & NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY
(SHRI SHRIPAD YESSO NAIK)

(a) & (b): Government has considered for setting up a central regulatory structure for AYUSH drugs. In this regard, it has been decided to have a vertical structure for AYUSH as a part of the Central Drugs Standard Control Organization (CDSCO) to enforce the regulatory provisions for Ayurvedic, Siddha, Unani and Homoeopathic drugs in coordination with the State regulatory authorities. Procedural steps for setting up this structure have been initiated but the actual timeframe for its operationalization is not specified at this stage.

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(c) to (e): Presently, there is no separate central agency for regulation of AYUSH drugs, except that the powers are vested with the Central Government to give directions to the State Governments and to make or amend rules for the licensing, manufacturing, and quality control of these drugs. The matter of setting up central vertical structure for AYUSH drugs in the CDSCO has been followed up regularly with the Department of Health & Family Welfare and 12 posts of Deputy Drugs Controllers, Assistant Drugs Controllers and Inspectors of Ayurvedic, Siddha, Unani (ASU) and Homoeopathy created in the Ministry of AYUSH. The Drugs and Cosmetics Act, 1940 and Rules thereunder have exclusive provisions for AYUSH drugs and particularly, the Rule 158-B of the Drugs & Cosmetics Rules, 1945 prescribes the regulatory requirements including submission of proof of safety and effectiveness for licensing of both classical and patent or proprietary ASU drugs. Compliance to the guidelines of Good Manufacturing Practices as provided in the Drugs & Cosmetics Rules, 1945 and quality standards of AYUSH drugs provided in the respective Pharmacopeias is mandatory for the manufacturers. Enforcement of these regulatory provisions is vested with the Licensing Authorities appointed by the State Governments.
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